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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/585,115	06/30/2006	Yehiel Ziv	1393GIT-US	5762

David Klein
Dekel Patent Ltd.
Beit HaRof'im
18 Menuha VeNahala Street, Room 27
Rehovot,
ISRAEL

7590 03/03/2009

EXAMINER

MEHMOOD, SEHAR BEENA

ART UNIT	PAPER NUMBER
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4118

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PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/585,115	Applicant(s) ZIV ET AL.	
	Examiner SEHAR MEHMOOD	Art Unit 4118	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 30 June 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-12 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-12 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 30 June 2006 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☒ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>6/30/2006</u> . | 6) <input type="checkbox"/> Other: _____ |

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DETAILED ACTION

Oath/Declaration

1. The oath or declaration is defective. A new oath or declaration in compliance with 37 CFR 1.67(a) identifying this application by application number and filing date is required. See MPEP §§ 602.01 and 602.02.

The oath or declaration is defective because:

It does not state that the person making the oath or declaration acknowledges the duty to disclose to the Office all information known to the person to be “material to **patentability** as defined in 37 CFR 1.56.”

Specification

Content of Specification

- (a) Title of the Invention: See 37 CFR 1.72(a) and MPEP § 606. The title of the invention should be placed at the top of the first page of the specification unless the title is provided in an application data sheet. The title of the invention should be brief but technically accurate and descriptive, preferably from two to seven words may not contain more than 500 characters.
- (b) Cross-References to Related Applications: See 37 CFR 1.78 and MPEP § 201.11.
- (c) Statement Regarding Federally Sponsored Research and Development: See MPEP § 310.
- (d) The Names Of The Parties To A Joint Research Agreement: See 37 CFR 1.71(g).
- (e) Incorporation-By-Reference Of Material Submitted On a Compact Disc: The specification is required to include an incorporation-by-reference of electronic documents that are to become part of the permanent United States Patent and Trademark Office records in the file of a patent application. See 37 CFR 1.52(e) and MPEP § 608.05. Computer program listings (37 CFR 1.96(c)), “Sequence Listings” (37 CFR 1.821(c)), and tables having more than 50 pages of text were permitted as electronic documents on compact discs beginning on September 8, 2000.

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- (f) Background of the Invention: See MPEP § 608.01(c). The specification should set forth the Background of the Invention in two parts:
- (1) Field of the Invention: A statement of the field of art to which the invention pertains. This statement may include a paraphrasing of the applicable U.S. patent classification definitions of the subject matter of the claimed invention. This item may also be titled "Technical Field."
 - (2) Description of the Related Art including information disclosed under 37 CFR 1.97 and 37 CFR 1.98: A description of the related art known to the applicant and including, if applicable, references to specific related art and problems involved in the prior art which are solved by the applicant's invention. This item may also be titled "Background Art."
- (g) Brief Summary of the Invention: See MPEP § 608.01(d). A brief summary or general statement of the invention as set forth in 37 CFR 1.73. The summary is separate and distinct from the abstract and is directed toward the invention rather than the disclosure as a whole. The summary may point out the advantages of the invention or how it solves problems previously existent in the prior art (and preferably indicated in the Background of the Invention). In chemical cases it should point out in general terms the utility of the invention. If possible, the nature and gist of the invention or the inventive concept should be set forth. Objects of the invention should be treated briefly and only to the extent that they contribute to an understanding of the invention.
- (h) Brief Description of the Several Views of the Drawing(s): See MPEP § 608.01(f). A reference to and brief description of the drawing(s) as set forth in 37 CFR 1.74.
- (i) Detailed Description of the Invention: See MPEP § 608.01(g). A description of the preferred embodiment(s) of the invention as required in 37 CFR 1.71. The description should be as short and specific as is necessary to describe the invention adequately and accurately. Where elements or groups of elements, compounds, and processes, which are conventional and generally widely known in the field of the invention described and their exact nature or type is not necessary for an understanding and use of the invention by a person skilled in the art, they should not be described in detail. However, where particularly complicated subject matter is involved or where the elements, compounds, or processes may not be commonly or widely known in the field, the specification should refer to another patent or readily available publication which adequately describes the subject matter.
- (j) Claim or Claims: See 37 CFR 1.75 and MPEP § 608.01(m). The claim or claims must commence on separate sheet or electronic page (37 CFR 1.52(b)(3)). Where a claim sets forth a plurality of elements or steps, each element or step of the claim should be separated by a line indentation. There may be plural indentations

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to further segregate subcombinations or related steps. See 37 CFR 1.75 and MPEP § 608.01(i)-(p).

- (k) Abstract of the Disclosure: See MPEP § 608.01(f). A brief narrative of the disclosure as a whole in a single paragraph of 150 words or less commencing on a separate sheet following the claims. In an international application which has entered the national stage (37 CFR 1.491(b)), the applicant need not submit an abstract commencing on a separate sheet if an abstract was published with the international application under PCT Article 21. The abstract that appears on the cover page of the pamphlet published by the International Bureau (IB) of the World Intellectual Property Organization (WIPO) is the abstract that will be used by the USPTO. See MPEP § 1893.03(e).
- (l) Sequence Listing. See 37 CFR 1.821-1.825 and MPEP §§ 2421-2431. The requirement for a sequence listing applies to all sequences disclosed in a given application, whether the sequences are claimed or not. See MPEP § 2421.02.

2. The disclosure is objected to because of the following informalities: Please see part b of “Content of Specification.” Priority not stated in the Specifications.

Appropriate correction is required.

3. The use of the trademark DACROM™ (page 4) has been noted in this application. It should be capitalized wherever it appears and be accompanied by the generic terminology.

Although the use of trademarks is permissible in patent applications, the proprietary nature of the marks should be respected and every effort made to prevent their use in any manner which might adversely affect their validity as trademarks.

Drawings

4. The drawings are objected to as failing to comply with 37 CFR 1.84(p)(5) because they do not include the following reference sign(s) mentioned in the description: Reference # 93 (Holding Member) as mentioned on page 4 of the specs (specifically referring to Figures 9A-D) . Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office

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action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

Claim Rejections - 35 USC § 102

5. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

6. Claims 1, 4-6 and 8 are rejected under 35 U.S.C. 102(e) as being anticipated by Feng et al. (US 6,752,754 B1).

7. Regarding Claim 1, Feng et al. discloses a gastrointestinal device (artificial rectum 10; Col 3, line 51; Figure 1) comprising: a casing (outer body 16; Col 3, lines 65-66; Figure 1)) comprising fixation elements (connector 32; Col 5, lines 54-56; Figure 1) adapted for intraluminal fixation of the device in the GI tract; a valve (inlet valve 40; Col 4, lines 27-29; Figure 1); and a controller (control unit 15; Col 3, lines 51-59; Figure 1) operatively connected to

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said valve for externally controlling the position of said valve between the closed and open positions.

8. Regarding Claim 4, Feng et al. discloses a valve comprising a flexible sleeve which is deformable in the closed and open positions (elastomeric (having the property of being elastic) check valve (Col 5, lines 22-24).

9. Regarding Claim 5, Feng et al. discloses controller being a shutter (100 and 102; Figure 6; Col 6, lines 43-67) attached to flexible sleeves, said shutters being selectively movable to cause said flexible sleeve to be in either closed or open positions.

10. Regarding Claim 6, Feng et al. discloses shutters 100 and 102 being actuated by fluid pressure via pressure sensors (Col. 4, line 61 – Col 5, line 3; Figure 1).

11. Regarding Claim 8, Feng et al. discloses a controller comprising a fluid inlet 36 (Col 4, line 28; Figure 1) adapted to apply fluid pressure (via pressure sensor) to said flexible sleeves (an increase and decrease in fluid pressure in spring loaded ball-check valve will cause the valve to open and close, thus releasing fluid or air in this instance (Col 5, lines 11-19)) to open and close flexible sleeves.

Claim Rejections - 35 USC § 103

12. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

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13. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

14. Claims 2-3 are rejected under 35 U.S.C. 103(a) as being unpatentable over Feng et al. in view of Brooks et al. (US 4,967,844).

15. Re Claims 2 and 3, Feng et al. discloses all of the claimed elements except for the valve being a ball valve rotatable between closed and open positions and the controller being at least one string attached to the ball valve, so that when the string is pulled, the ball valve rotates. Brooks et al. teaches the ball valve being rotatable between open and closed positions (Col 2, lines 64-66). Brooks et al. also teaches a string being attached to the ball valve assembly so that it rotates when pulled (Col 2, lines 63-68). Therefore, it would have been obvious to one skilled in the art at the time the invention was made to modify Feng et al. to include a ball valve (common valve for fluid flow control and Feng et al. states “valve 40 may take the form of any of numerous different types of valves....for performing the function of the valve as described herein.” Col 6, lines 64-67) with a string for opening and closing, as taught by Brooks et al., in order to easily and manually control the flow of waste matter through the device.

16. Claims 7 is rejected under 35 U.S.C. 103(a) as being unpatentable over Feng et al. in view of Carter et al. (US 5,593,443).

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17. Re Claim 7, Feng et al. discloses all of the claimed elements except for the controller comprising an inflatable member positioned about flexible sleeve, where the inflation and deflation of the inflatable member corresponds with the closing and opening of the flexible sleeve, respectively. Carter et al. teaches a pump and valve 20 and conduit 18 inflate a liquid filled tube (inflatable member) which pressed against the anal canal (effectively, causing the wall to be a "flap" or "flexible sleeve" valve and the inflating and deflating the tube with liquid "opens and closes" the "valve")(Col 5, lines 33-37). Therefore, it would have been obvious to one skilled in the art at the time the invention was made to modify Feng et al. to include an inflatable member, as taught by Carter et al., in order to provide an alternative way of controlling flow of fecal matter through the GI tract.

18. Claims 9-12 are rejected under 35 U.S.C. 103(a) as being unpatentable over Feng et al. in view of Kagan et al. (US 2004/0092892).

19. Re Claims 9 and 10, Feng et al. discloses all of the claimed elements except for the fixation elements being rotatable hooks or barbs. Kagan et al. teaches the use of hooks or other known fasteners (such as barbs, which are used interchangeably with hooks) for attaching a gastrointestinal sleeve device 400 (Figures 23A) into position (Paragraph [0276], lines 8-10). Therefore, it would have been obvious to one skilled in the art at the time the invention was made to modify Feng et al. to include hooks or barbs as fixation elements, as taught by Kagan et al., in order to secure the gastrointestinal device in position in an alternative way asides from suturing (Figures 23A and 42B).

20. Re Claims 11 and 12, Feng et al. discloses all of the claimed elements except for an insertion assist device adapted to move said fixation elements to a fixed position in the GI tract

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or the insertion assist device comprises a trigger that actuates grabbers to rotate the rotatable hooks. Kagan et al. teaches an insertion assist device (surgical instrument 700) placing fixation elements (fasteners 710) into a fixed position (Paragraph [0394], lines 1-9; Figures 49-51).

Additionally, Kagan et al. teaches a trigger (control button 718; paragraph [0394], lines 27-28; Figures 49-51) that actuates a grabber (articulated arm 706; paragraph [0394], lines 7-9; Figures 49-51). Therefore, it would have been obvious to one skilled in the art at the time the invention was made to modify Feng et al. to include the elements of the insertion assist device, as taught by Kagan et al., for the purpose of facilitating the placement of connectors/fixation elements inside the patient's body.

Conclusion

21. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Meah (US 6,432,040).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to SEHAR MEHMOOD whose telephone number is (571)270-7857. The examiner can normally be reached on Monday-Friday 9am-5pm EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Quang Thanh can be reached on (571)272-4982. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/S. M./
Examiner, Art Unit 4118

/Quang D. Thanh/
Supervisory Patent Examiner, Art Unit
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